SCHEDULING STATUS

S4

CONTREZ

(Film-coated tablets)

Ethinylestradiol (0,02 mg) and drospirenone (3 mg) tablets

(active tablets).

Active tablets contain sugar: lactose monohydrate

(43,303 mg)

Inactive tablets (placebo) contain sugar: lactose

monohydrate (60,00 mg)

Read all this leaflet carefully before you start taking CONTREZ

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- **CONTREZ** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **CONTREZ** is and what it is used for

2. What you need to know before you take **CONTREZ**

3. How to take **CONTREZ**

4. Possible side effects

5. How to store **CONTREZ**

6. Contents of the pack and other information

1. What CONTREZ is and what is it used for:

CONTREZ is a combined oral contraceptive ("the combined tablet") consisting of 24 pink tablets with active ingredients and 4 white inactive tablets. Each active tablet contains a small amount of two different female hormones. These are drospirenone (a progesterone) and ethinylestradiol (an oestrogen). Because of the small amounts of hormones, **CONTREZ** is considered a low-dose oral contraceptive. **CONTREZ** is used:

- to prevent pregnancy.
- for the treatment of moderate acne vulgaris in women seeking oral contraception.
- for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who have chosen oral contraceptives as their method of birth control.

2. What you need to know before you take CONTREZ :

Do not take CONTREZ if you:

- are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of **CONTREZ** (listed in section 6). This may cause itching, rash or swelling.
- have (or had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs.

- know you have a disorder affecting your blood clotting (for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden, or antiphospholipid antibodies).
- Have (or had) a blood clot in your arteries (arterial thromboembolism).
- need an operation or if you are off your feet for a long time (see section ‘Blood clots’).
- have ever had a heart attack or stroke.
- have (or had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms).
- have any of the following diseases that may increase your risk of a clot in the arteries:
    - severe diabetes with blood vessel damage
    - very high blood pressure
    - a very high level of fat in the blood (cholesterol or triglycerides)
    - a condition known as hyperhomocysteinaemia (a condition that can lead to arterial damage and blood clots in your blood vessel).
- have (or had) a type of migraine called ‘migraine with aura’.
- have (or had) a liver disease and your liver function is still not normal.
- kidneys are not working well (renal failure).
- have (or had) a tumour in the liver.
- have (or had) or if you are suspected of having breast cancer or cancer of the genital organs.
- have any unexplained bleeding from the vagina.

- have inflammation of the liver (hepatitis C) and are taking the **CONTREZ** containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section "Other medicines and **CONTREZ** ").

Warnings and precautions

Tell your doctor or health care provider if:

- you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clots' section below). *For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot"*
- a close relative has or has ever had breast cancer
- you have a disease of the liver or the gallbladder
- you have diabetes
- you have depression
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).
- you have systemic lupus erythematosus (SLE - a disease affecting your natural defence system).
- you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of kidneys).
- you have sickle cell anaemia (an inherited disease of the red blood cells).
- you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been

associated with an increased risk of developing pancreatitis (inflammation of the pancreas).

- you need an operation, or you are off your feet for a long time (see in section 2 ‘Blood clots’).
- if you have just given birth, you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking **CONTREZ** .
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- If you have varicose veins.
- if you have epilepsy (see “Other medicines and **CONTREZ** ”)
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham’s chorea).
- if you have or have ever had golden brown pigment patches (chloasma), so called “pregnancy patches”, especially on the face. If this is the case, avoid direct exposure to sunlight or ultraviolet light.
- If you have inherited angioedema, products containing oestrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.

BLOOD CLOTS

Using a combined hormonal contraceptive such as **CONTREZ** increases your risk of developing a **blood clot** compared with not using one. In rare cases a blood clot can block vessels and cause serious problems.

Blood clots can develop:

- in veins (referred to as a ‘venous thrombosis’, ‘venous thromboembolism’ or VTE).
- in the arteries (referred to as an ‘arterial thrombosis’, ‘arterial thromboembolism’ or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to CONTREZ is small.

Blood clots in a vein

What can happen if a blood clot forms in a vein?

- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop **CONTREZ** your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with **CONTREZ** is small.

The risk of a blood clot with **CONTREZ** is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30 kg/m^2).
- if one of your immediate family has had a blood clot in the leg, lung, or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder.
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of **CONTREZ** may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop **CONTREZ** ask your doctor when you can start using it again.

- as you get older (particularly above about 35 years).
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

Air travel (> 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that **CONTREZ** needs to be stopped.

If any of the above conditions change while you are using **CONTREZ** , for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

Blood clots in an artery

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery

It is important to note that the risk of a heart attack or stroke from using **CONTREZ** is very small but can increase:

- with increasing age (beyond about 35 years).
- if you smoke, when using a combined hormonal contraceptive like **CONTREZ** , you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive.
- if you are overweight.

- if you have high blood pressure.
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke.
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides).
- if you get migraines, especially migraines with aura.
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation).
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.
If any of the above conditions change while you are using **CONTREZ** , for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

How to recognise a blood clot

Seek urgent medical attention if you notice any of the following signs or symptoms.

You could possibly be suffering from deep vein thrombosis if you are experiencing any of these signs:

- swelling of one leg or along a vein in the leg or foot especially when accompanied by:

- pain or tenderness in the leg which may be felt only when standing or walking
- increased warmth in the affected leg
- change in colour of the skin on the leg e.g. turning pale, red, or blue

You could possibly be suffering from pulmonary embolism if you are experiencing any of these signs:

- sudden unexplained breathlessness or rapid breathing.
- sudden cough without an obvious cause, which may bring up blood.
- sharp chest pain which may increase with deep breathing.
- severe light headedness or dizziness.
- rapid or irregular heartbeat
- severe pain in your stomach.

If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a ‘common cold’).

You could possibly be suffering from a heart attack if you are experiencing any of these signs:

- chest pain, discomfort, pressure, heaviness
- sensation of squeezing or fullness in the chest, arm or below the breastbone.
- fullness, indigestion or choking feeling.
- upper body discomfort radiating to the back, jaw, throat, arm and stomach.
- sweating, nausea, vomiting or dizziness.
- extreme weakness, anxiety, or shortness of breath.

- rapid or irregular heartbeats

You could possibly be suffering from a stroke if you are experiencing any of these signs:

- sudden weakness or numbness of the face, arm, or leg, especially on one side of the body.
- sudden confusion, trouble speaking or understanding.
- sudden trouble seeing in one or both eyes.
- sudden trouble walking, dizziness, loss of balance or coordination.
- sudden, severe, or prolonged headache with no known cause.
- loss of consciousness or fainting with or without seizure.

Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.

CONTREZ and cancer

Breast cancer has been observed slightly more often in women using combination pills like in **CONTREZ** , but it is not known whether this is caused by the treatment. For example, it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives like **CONTREZ** . It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In a very few cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

Psychiatric disorders

Some women using hormonal contraceptives including **CONTREZ** have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Bleeding between periods

During the first few months that you are taking **CONTREZ** , you may have unexpected bleeding (bleeding outside the placebo days). If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

What you must do if no bleeding occurs during the placebo days

If you have taken all the light pink active tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Only start the next strip if you are sure that you are not pregnant.

Special populations

Children and adolescents

CONTREZ is not intended for use in females whose periods have not yet started.

Older women

CONTREZ is not intended for use after the menopause.

Women with liver impairment

Do not take **CONTREZ** if you suffer from liver disease. See also sections 'Do not take **CONTREZ** ' and 'Warnings and precautions'.

Women with kidney impairment

Do not take **CONTREZ** if you are suffering from poorly functioning kidneys or acute kidney failure. See also sections '**CONTREZ** ' and 'Warnings and precautions'

Other medicines and CONTREZ :

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines). This includes medicines used for the treatment of:

- bacterial infections (antibiotics e.g. penicillin, tetracyclines, griseofulvin)

- epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
- tuberculosis (e.g. rifampicin)
- HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
- fungal infections (e.g. griseofulvin, ketoconazole)
- arthritis, arthrosis (e.g. etoricoxib)
- high blood pressure in the blood vessels in the lungs (e.g. bosentan)
- the herbal remedy St. John's wort

CONTREZ *may* ***influence the effect*** *of other medicines, e.g.*

- immunosuppressant medicines containing ciclosporin which can be used in patients suffering from rheumatoid arthritis.
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).
- theophylline (used to treat breathing problems).
- tizanidine (used to treat muscle pain and/or muscle cramps).

- Do not use **CONTREZ** if you have hepatitis C and are taking the **CONTREZ** containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicines. **CONTREZ** can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use **CONTREZ** ".

CONTREZ with food, drink, and alcohol:

CONTREZ may be taken with or without food, if necessary, with a small amount of water.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

If you are pregnant, you must not take **CONTREZ** . If you become pregnant while taking **CONTREZ ,** you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking **CONTREZ** at any time (see also “If you stop taking **CONTREZ** ”).

Breast-feeding

Use of **CONTREZ** is generally not advisable when a woman is breast-feeding

Driving and using machines:

CONTREZ can cause dizziness (a feeling of unsteadiness) which can influence your ability to drive or use machinery (See section 4. Possible side effects).

It is not always possible to predict to what extent **CONTREZ** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **CONTREZ** affects them.

CONTREZ contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CONTREZ.

3. How to take CONTREZ :

Do not share medicines prescribed for you with any other person.

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

The **CONTREZ** pack contains 28 tablets (24 active tablets and 4 inactive tablets). The first course of **CONTREZ** is started on the first day of the menstrual period (day 1 of the cycle) from the silver section of the pack by selecting the appropriate tablet for that day of the week (e.g. “MO” for Monday) The tablet is swallowed whole with some liquid. Thereafter one tablet must be taken daily for 28 days following the direction shown by the arrows. It does not matter at what time of the day the tablet is taken, but once you have selected a particular time, the tablet should be taken as near as possible at the same time each day. Withdrawal bleeding usually starts on day 2 or 3 after starting the inactive tablets and may not have finished before the next pack is started. Each subsequent pack is started in the silver section the day after the last tablet of the current pack. If you start **CONTREZ** during the latter part of the week, the first cycle may be slightly shortened.

Starting your first pack of CONTREZ :

When no hormonal contraceptive has been used in the past month:

Start taking **CONTREZ** on the first day of your cycle, i.e. the first day of menstrual bleeding. Take the tablet marked with that day of the week from the silver section of the pack. For example, if your period starts on a Friday, take the tablet marked “FR”. Then take 1 tablet every day following the directions shown by the arrows. During the first cycle an additional barrier method is recommended for the first 7 days of tablet-taking.

When changing from another combined tablet, vaginal ring or transdermal (contraceptive) patch:

You should start with **CONTREZ** preferably on the day after the last active tablets of your previous combined oral contraceptive, but at the latest on the day following the usual inactive tablet interval of your previous combined oral contraceptive. In case you have used a vaginal ring or transdermal patch, you should start using **CONTREZ** preferably on the day of removal, but at the latest when the next application would have been due. If you follow these instructions, it is not necessary to use an additional contraceptive barrier method.

When changing from a progestogen-only method (minitablet, injection, implant) as from a progestogen-releasing intrauterine system (IUS):

You may switch any day from the minipill, from an implant or the IUS on the day of its removal, and from an injectable when the next injection would be due, but in all these cases you are advised to use an additional barrier method for the first 7 days of tablet-taking.

After having a baby:

If you are breastfeeding and want to take **CONTREZ** , you should discuss this first with your doctor, who will advise you.

After a miscarriage or an abortion:

Your doctor will advise you on how to take **CONTREZ** after a miscarriage or an abortion.

If you take more CONTREZ than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken **CONTREZ** , ask your doctor for advice. Taking the white tablets from the bottom row of the blister is harmless because they do not contain active ingredients.

If you forget to take a dose of CONTREZ :

- If you are **less than 12 hours late** in taking an active tablet, the reliability of the tablet is maintained. Take the tablet as soon as you remember and take the next tablet at the usual time.
- If you are **more than 12 hours late** in taking any active tablet, the reliability of the tablet may be reduced. The more consecutive active tablets you have missed, the higher the risk that the contraceptive effect is decreased. There is

particularly high risk of becoming pregnant if you miss tablets in the week before or in the week after the inactive tablets. Therefore, you should follow the rules given below.

More than one tablet forgotten in a pack:

Ask your doctor for advice.

1 tablet missed in the first 7 days of active tablet-taking (1st 7 days after the inactive tablets):

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablet at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days.

If you have had sexual intercourse in the week before missing the tablet, there is a possibility of becoming pregnant, so tell your doctor immediately.

1 tablet missed in the second 7 days of active tablet-taking:

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablet at the usual time.

Provided that you have taken all your tablets correctly in the 7 days before the missed tablet, reliability of the tablet is maintained, and you need not use extra contraceptive precautions. If this is not the case use extra precautions for 7 days.

1 tablet missed in the third 7 days of active tablet-taking (the last 7 days before the inactive tablets):

You may choose either of the following options, without the need for extra contraceptive precautions.

1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time until the active tablets are used up. The 4 inactive tablets must be discarded (i.e. discard the current pack after taking the last pink tablet on “FR”). Start the next pack right away, with the first pink tablet from the silver section. You may not have a withdrawal bleed until the end of the active tablets in the second pack, but you may have spotting or breakthrough bleeding on active tablet-taking days.

   or

2. Stop taking tablets from your current pack, have a tablet-free break of 4 days or less **(also count the day you missed your tablet)** and then continue with the next pack, starting in the silver section with the pink active tablet for the appropriate day of the week.

If you have forgotten tablets in a pack and you do not have your period as expected, you may be pregnant. Consult your doctor before you start the next pack.

What to do if you forget tablets:

More than 1 active tablet forgotten in a cycle:

Ask your doctor for advice.

Only 1 pink tablet forgotten (more than 12 hours late):

First 7 days of active (pink) tablet-taking:

If you had sex in the week before missing:

Ask your doctor.

If you did not have sex in the week before missing:

- Take the missed tablet
- Use extra precautions for 7 days and
- Complete the pack

Second 7 days of active (pink) tablet-taking:

- Take the missed tablet
- Complete the pack

Third 7 days of active (pink) tablet-taking:

1. – Take the missed tablet
   - Complete the active pink tablets
   - Skip the inactive white tablets
   - Continue with the next pack with the first pink “WE” tablet from the silver section.

   OR
2. – Stop the current pack
   - Have a tablet-free break (not more than 4 days including missed tablet days)
   - Continue with the next pack, starting in the silver section with the pink active tablet for the appropriate day of the week.

Taking the inactive- tablet:

The white tablets are inactive tablets and missing these can be disregarded. However, the missed inactive tablets should be discarded to avoid unintentionally prolonging the inactive tablet phase.

What to do if:

You suffer from gastro-intestinal disturbances (e.g. vomiting, severe diarrhoea):

If you vomit, or have severe diarrhoea after taking active tablets, the active ingredients in your **CONTREZ** tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. Therefore, follow the advice for missed tablets. If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking tablets from the inactive white tablets does not have an influence on the contraceptive reliability.

You want to delay a period:

You can delay your period if you start with your next pack of **CONTREZ** tablets immediately after finishing the active pink tablets of your current pack (do not take the inactive white tablets). You can continue with this pack for as long as you wish, e.g. until this pack is empty, to get a period approximately 3 weeks later than usual. While using the second pack you may have some breakthrough bleeding or spotting on active tablet-taking days.

You have unexpected bleeding:

With all tablets, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the tablet (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

You have missed a period:

If you have missed a period, consult your doctor.

If you stop taking CONTREZ

You can stop taking **CONTREZ** at any time you want, if you stop because you want to get pregnant. It is generally recommended that you wait until you have had a natural period before trying to fall pregnant. This helps you to estimate when the baby will be due.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

4. Possible side effects

CONTREZ can have side effects.

Not all side-effects reported for **CONTREZ** are included in this leaflet. Should your general health worsen while taking **CONTREZ**, or if you experience any untoward effects while taking **CONTREZ** please consult your doctor, pharmacist, or other healthcare provider for advice.

If any of the following happens, stop taking **CONTREZ** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- ‘Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing’,
- Rash or itching,
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to **CONTREZ**. You may need urgent medical attention or hospitalisation

Tell your doctor if you notice any of the following:

Frequent side effects:

- mood swings
- headache
- nausea
- breast pain, problems with your periods, such as irregular periods, absence of period.
- vaginal discharge.

Less frequent side effects:

- depression, nervousness, sleepiness
- dizziness, ‘pins and needles’
- migraine, varicose veins, increased blood pressure
- stomachache, vomiting, indigestion, intestinal gas, inflammation of the stomach, diarrhoea
- acne, itching, rash
- aches and pains, e.g. back pain, limb pain, muscle cramps
- vaginal fungal infection, pelvic pain, breast enlargement, benign breast lumps, uterine/vaginal bleeding (which usually subsides during continued treatment), genital discharge, hot flushes, inflammation of the vagina (vaginitis), problems with your periods, painful periods, reduced periods, very heavy periods, vaginal dryness, abnormal cervical smear, decreased interest in sex
- lack of energy, increased sweating, fluid retention

- weight increase
- candida (fungal infection)
- anaemia, increase in the number of platelets in the blood
- hormonal (endocrine) disorder
- increased appetite, loss of appetite, abnormally high concentration of potassium in the blood, abnormally low concentration of sodium in the blood
- failure to experience an orgasm, insomnia
- giddiness, tremor
- eye disorders, e.g. inflammation of the eyelid, dry eyes
- hearing problems,
- inflammation of a vein, nosebleed, fainting
- enlarged abdomen, bowel disorder, feeling bloated, stomach hernia, fungal infection of the mouth, constipation, dry mouth
- high blood pressure,
- low blood pressure,
- pain of bile ducts or the gallbladder, inflammation of the gallbladder
- yellow brown patches on the skin, eczema, hair loss, acne-like inflammation of the skin, dry skin, lumpy inflammation of the skin, excessive hair growth, skin disorder, stretch marks on the skin, skin inflammation, light-sensitive skin inflammation, skin nodules
- difficult or painful sex, inflammation of the vagina (vulvovaginitis), bleeding following intercourse, withdrawal bleeding, breast cyst, increased number

of breast cells (hyperplasia), malignant lumps in the breast, abnormal growth on the mucosal surface of the neck of the womb, shrinkage or wasting of the lining of the womb, ovarian cysts, enlargement of the womb

- feeling generally unwell
- weight loss
- harmful blood clots in a vein or artery for example:
- in a leg or foot (i.e. DVT)
- in a lung (i.e. PE)
- heart attack
- stroke
- mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
- blood clots in the liver, stomach/intestine, kidneys, or eye

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse drug Reaction reporting Form", found online under SAHPRA's publications : https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **CONTREZ** .

5. How to store CONTREZ

- Keep out of reach and sight of children.

- Store at or below 30ºc.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

CONTREZ (film-coated tablets) contains:

The active substance: 3 mg drospirenone and 0,02 mg ethinylestradiol.

The other ingredients are: Croscarmellose sodium, hypromellose, iron oxide red, lactose monohydrate magnesium stearate, macrogol, maize starch, povidone, pregelatinised starch, purified water, titanium dioxide.

What CONTREZ looks like and contents of the pack

Film-coated tablets

CONTREZ 3 mg/0.02 mg (Active tablets)

Light pink, circular biconvex film-coated tablets embossed with “D2” on one side and plain on the other side.

Placebo (inactive tablets)

White, circular, biconvex film-coated tablets embossed with “PC” on one side and plain on the other side.

CONTREZ 3 mg/0.02 mg

Blisters of 24 hormonal tablets and 4 placebo tablets made of PVC/ aluminum foil. The blisters are packaged in a carton box along with package insert.

Holder of Certificate of Registration

Innovata Pharmaceuticals

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Ormonde

Johannesburg

2091

South Africa

This leaflet was revised in

02/09/2025

Registration number

A 50/21.8.2/0517

Access to the corresponding Professional information.

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